In accordance with the provisions of 37 C.F.R. §1.121(c)(1)(i), please amend claims 14 and 17 to read as follows.

C3

14. (Amended) The method of claim 17 wherein the binding agent is a monoclonal antibody produced by a hybridoma that has ATCC Designation Number HB-12526.

C4

17. (Twice Amended) A method for inducing an immune response to prostate specific antigen comprising administering a binding agent to a patient with prostate cancer, wherein the binding agent specifically binds to an epitope of circulating prostate specific antigen, the epitope being specifically bound by a monoclonal antibody produced by a hybridoma that has ATCC Designation Number HB-12526, the binding agent being capable of binding to the antigen to form an immunogenic binding agent-antigen complex.

REMARKS

Claims 14, 15, 17, 20, and 21 are pending.

Claims 28-34 have been added to cover methods for inducing host production of an anti-PSA antibody by administering a binding agent that specifically binds to an epitope on circulating prostate specific antigen to the host, wherein the epitope is specifically bound by a monoclonal antibody produced by a hybridoma that has ATCC Designation Number HB-12526. Support for these new claims can be found throughout the specification; for example, at page 7, lines 18-30; at page 26, lines 1-8 (*i.e.*, Example 6); and in Figure 8.

Claim 14 has been amended to correct inadvertent typographical errors.

Claim 17 has been amended to cover methods for inducing an immune response to prostate specific antigen comprising administering a binding agent that specifically binds to an epitope on circulating prostate specific antigen, wherein the epitope is specifically bound by a monoclonal antibody produced by a hybridoma that has ATCC Designation Number HB-12526. Support for this claim amendment can be found throughout the specification, for example, at page 11, lines 13-22.

Claim 17 has also been amended to specify that the patient has prostate cancer. Support for this claim amendment can be found throughout the specification, for example, at page 10, lines 3-15.

Pursuant to the provisions of 37 C.F.R. §1.121(c)(1)(ii), a marked-up copy of amended claims 14 and 17 is attached herewith as Appendix A.

The specification has been amended at page 17 to provide the deposit information for hybridoma clone AR47.47.

None of the above amendments adds any new matter to the Application as filed.

I. Supplemental Information Disclosure Statement

The Office Action has asserted that the references in the Supplemental Information Disclosure Statement were not received, and thus could not be examined.

In response, on September 26, 2001, Applicants resubmitted the Supplemental Information Disclosure Statement together with copies of the references listed on the PTO 1449 form. Applicants respectfully request examination of these references.

II. Priority

Applicants thank the Examiner for acknowledging that the Application has a priority date of June 15, 1998.

III. The Application Complies with the Deposit Requirement

Claim 14 stands rejected under 35 U.S.C. §112, first paragraph, because the deposit requirement of hybridoma cell line AR47.47 has not been met.

Applicants are herewith resubmitting as Appendix B a copy of the Deposit Receipt for American Type Culture Collection Designation No. HB-12526 (previously submitted in Applicants' communication dated March 5, 2001).

As agent of record, I declare the following:

Applicants have deposited the hybridoma producing the monoclonal antibody, AR47.47, with the American Type Culture Collection (ATCC) in accordance with the provisions of the Budapest Treaty.

Attached as Appendix B is a copy of the deposit receipt from the ATCC. As can be seen, the ATCC has assigned the hybridoma producing the monoclonal antibody, AR47.47, the designation number of HB-12526. All restrictions upon public access to the deposits will be irrevocably removed upon granting of a patent from this Application.

Moreover, as requested by the Office Action, the specification has been presently amended to add identifying information for the deposit of the hybridoma producing the monoclonal antibody, AR47.47 pursuant to the provisions of 37 C.F.R. §1.809(d).

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

IV. The Application Complies With 35 U.S.C. §112, First Paragraph

New Matter

Claim 17, and the claims dependent thereon, stand rejected under 35 U.S.C. §112, first paragraph, as containing new matter.

Applicants have overcome this ground for rejection by the present amendment to claim 17. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

Enablement

Claims 14, 15, 17, 20, and 21 stand rejected under 35 U.S.C. §112, first paragraph, as being non-enabled (Office Action, page 4).

Applicants respectfully traverse this ground of rejection.

Applicants' invention stems from their discovery that administration of a binding agent that specifically binds circulating prostate specific antigen to a host will generate in that host the production of prostate specific antigen-specific antibodies. The host need not be suffering from prostate cancer nor have any circulating prostate specific antigen (see, *e.g.*, specification at page 1, lines 19-25; and Examples 5-6 in specification at page 24, line 17 through page 26, line 8). Accordingly, Applicants have added new claims 28-34 to cover this aspect of the invention which involves administration of the binding agent, as claimed, to "prostate cancer free" hosts.

However, methods for administering the claimed binding agent to a patient that does, in fact, have prostate cancer is also enabled by the Application. Applicants have demonstrated in Example 7 that upon administration of a binding agent, as claimed, "the tumor burden of mice immunized with anti-PSA MAb was considerably lower compared to the group of mice immunized with control antibody." (Application at page 26, lines 19-20). Moreover, as shown in the far right graph of Figure 9, the number of tumor foci was reduced in those immunized mice which, following immunization, generated their own anti-PSA antibodies ("Ab3"). Likewise, Applicants have demonstrated in Example 11 that tumor burden is reduced in animals treated with AR47.47, as compared to those animals treated with control antibody or PBS (see, *e.g.*, page 36, lines 6-8).

The Examiner has stated that because AR47.47 was administered before tumor inoculation, this example does not enable the claimed invention.

Applicants respectfully direct the Examiner's attention to page 36, lines 11-14. There, the specification states, "The positive signal obtained for Ab3 in the control groups (PBS and control mab) is not surprising since the release of human PSA by the growing tumor in vivo will induce an anti-PSA immune response."

Applicants respectfully aver that the ordinarily skilled artisan would understand, upon reading the Application, that if the methods described in Example 11 had been performed in an animal already inoculated with tumor cells, the therapeutic effect of AR47.47 upon tumor burden would have been disguised, since the animal itself would have been making its own anti-PSA antibodies which would then compete with AR47.47 in binding to circulating PSA. This is why no therapeutic effect was observed in Example 12.

Thus, Applicants respectfully posit that one of skill in the art would know, upon reading in the Application that administration of AR47.47 induces anti-PSA antibodies in a prostate cancer-free host, that administration of AR47.47 to a prostate cancer patient would likewise induce anti-PSA antibodies in the prostate cancer patient.

Based on these remarks, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

Scope

Claims 15, 17, 20, and 21 stand rejected under 35 U.S.C. §112, first paragraph, because the scope of the claims are not reasonably correlated with the scope of enablement (Office Action, page 6).

Applicants respectfully traverse this ground for rejection.

As discussed above, the Application enables the generation in a host of both Ab2 antibodies (which resemble PSA) and Ab3 antibodies (which specifically bind to PSA) upon administration of a binding agent that specifically binds to the epitope on circulating PSA that is specifically bound by the monoclonal antibody produced by a hybridoma having ATCC Designation Number HB-12526 (*i.e.*, AR47.47). While the Application describes the administration of AR47.47 as the binding agent, Applicants respectfully aver that any ordinarily skilled artisan would understand that any binding agent, as described in the Application at page 10, line 16 through page 11, line 12, that specifically bound to the same epitope to which AR47.47 specifically binds, would accomplish the same result (*i.e.*, induction in the administered host of anti-PSA antibodies).

To limit Applicants to their examplary binding agent would be unjust considering the scope of what is taught in the Application and what was known in the art at the time the Application was filed. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

V. The Application Complies With 35 U.S.C. §102

Claim 14, 15, and 17 stand rejected as being anticipated by Giri *et al.*, European Patent Application No. 0 652 014 (hereinafter "Giri").

Applicants have overcome this ground for rejection by the present amendment to claim 17, upon which claims 14 and 15 depend. Giri nowhere teaches a binding agent that specifically binds to an epitope that is specifically bound by an antibody produced by a hybridoma having ATCC Designation Number HB-12526, as required by the claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

VI. The Application Complies With 35 U.S.C. §103

Claims 14, 15, 17, 20, and 21 stand rejected under 35 U.S.C. §103 as being unpatentable over Giri in view of Masuzawa *et al.*, *Neuroscience Res.* **18**: 27-34, 1993 (hereinafter "Masuzawa").

Applicants respectfully traverse this ground for rejection.

Applicants have presently amended claim 17 to require a binding agent that specifically binds an epitope that can be specifically bound by an antibody produced by a hybridoma having ATCC Designation Number HB-12526, as required by the claims. As all of claims 14, 15, 20, and 21 depend either directly or indirectly upon claim 17, they likewise require a binding agent that specifically binds such an epitope.

As discussed above, Giri nowhere teaches a binding agent that specifically binds to an epitope that can be specifically bound by an antibody produced by a hybridoma having ATCC Designation Number HB-12526, as required by the claims. Moreover, nowhere does Giri even suggest such a binding agent having the specificity set forth in the amended claim.

Nor do the teachings of Masuzawa cure this deficiency—nowhere does Masuzawa teach or suggest a binding agent that specifically binds to an epitope that can be specifically bound by an antibody produced by a hybridoma having ATCC Designation Number HB-12526, as required by the claims. In fact, nowhere does Mazuwa teach or suggest a binding agent that specifically binds to any epitope of prostate specific antigen.

Since neither Giri nor Masuzawa teach or suggest a binding agent that specifically binds to an epitope that can be specifically bound by an antibody produced by a hybridoma having ATCC Designation Number HB-12526, as required by the claims, as is required by the claims, their combination (even if the ordinarily skilled artisan were motivated to combine their teachings) cannot teach or suggest such a binding agent. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

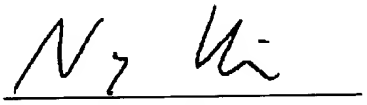
CONCLUSION

For the reasons stated above, Applicants respectfully submit that the claims are now ready for allowance. If the Examiner believes that any further discussion of this communication would be helpful, she is encouraged to contact the undersigned by telephone.

As the number of new claims is below the number of claims previously paid for by the Applicants when the Application was filed, Applicants believe no fee is due for the addition of the new claims.

No additional fees are believed to be due in connection with this communication. However, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,
HALE AND DORR LLP



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Date: January 4, 2002

APPENDIX A

Marked-up Version of the Amended Claims Pursuant to 37 C.F.R. §1.121(c)(1)(ii)

14. (Twice Amended) The method of claim 17 wherein the binding agent is a monoclonal antibody produced by a hybridoma that has ATCC [Accession] Designation Number HB-12526.

17. (Twice Amended) A method for inducing an immune response to prostate specific antigen comprising administering a binding agent to a patient with prostate cancer, wherein the binding agent specifically binds to an epitope of circulating prostate specific antigen, the epitope [comprising the sequence of SEQ ID NO:1] being specifically bound by a monoclonal antibody produced by a hybridoma that has ATCC Designation Number HB-12526, the binding agent being capable of binding to the antigen to form an immunogenic binding agent-antigen complex.

APPENDIX B

ATCC DEPOSIT RECEIPT

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

University of Alberta
Attn: Dr. B. Leveugle
3118 Dentistry Pharmacy CTR
Edmonton, Alberta T6G 2N8
Canada

Deposited on Behalf of: AltaRex Corp.

Identification Reference by Depositor:	**ATCC Designation**
Mouse hybridoma AR 47.47	HB-12526

The deposit was accompanied by: ___ a scientific description __ a proposed taxonomic description indicated above. The deposit was received April 29, 1998 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested June 1, 1998. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey

Barbara M. Hailey, Administrator, Patent Depository

Date: June 24, 1998

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JUL 03 1998

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JUL 0 1998